

Custom Imaging Methodology for Chronic Rhinosinusitis (CRS) Studies

CHALLENGE

The sponsor needed an objective imaging endpoint that correlates well with clinical outcomes for their two FDA-regulated
Phase III CRS trials.

MMI ACTIONS

MMI developed, validated, and integrated a 3-D analysis methodology to accurately quantify changes in sinus volume and CRS burden.

RESULT

The trials demonstrated reduced sinus inflammation using volumetric analysis as a co-primary endpoint, leading to FDA approval of the XHANCE product.

EPILOGUE

Sinus volumetric analysis is now the gold standard for CRS trials.

USEFUL LINKS

- ReOpen CRS Clinical Trial: <u>Press Release</u>
- Publication on 3-D sinus volumetric analysis, correlation to clinical outcomes, and comparison to Lund-Mackay scoring (<u>PubMed</u>)



MMI was a pivotal partner in this clinical development program.

They worked alongside us in not only developing the methodology, but we worked hand in hand as the trials were ongoing to ensure that the imaging analysis was done at the highest standards.

-- John Messina, Optinose Sr. VP Clinical Research & Medical Affairs